REMARKS

Reconsideration of this application and entry of this Amendment are requested. Claims 1-32 and 34 will be active in the application subsequent to entry of this Amendment.

The claims have been amended in order to more particularly point out and distinctly claim that which applicants regard as their invention and to direct the claims to a preferred aspect of the disclosure, as discussed in more detail below.

In the Official Action various claims have been rejected as either being anticipated by or rendered obvious over the disclosure of Allen et al US 6,334,856 optionally with Wurm et al US 5,484,720. See items 1-6 of the Action. On pages 5-6 of the Official Action the examiner explains his position with regard to the availability of the Allen et al "patent" as prior art. While applicants do not necessarily agree with the examiner's views, the claims have been amended in order to distinguish from the disclosures of the document cited and to advance prosecution generally.

Addressing more specifically the examiner's comments, the examiner states (page 5, paragraph 2i, of the Office Action) that US 6,334,856 has an effective date of 10 June 1998 and is available as prior art under 35 USC §102(e). This is limited to such information that is common to both the 10 June 1998 application and US '856. Information which is present in US '856 and not present in the 10 June 1998 application is not available as prior art; this is because it would have a relevant date, later than applicant's priority filing, of 21 May 1999.

Independent claims 1, 17, and 27 have been amended; "porous or polycrystalline silicon" is replaced by "resorbable silicon" the subject of original claim 2, now also amended. New claim 34 is added specifying the article of claim 17 in which the resorbable silicon comprises polycrystalline silicon and is similar to the amendment made to claim 2. These amendments are based on the text at page 11, lines 1 to 5 of applicant's specification, a preferred aspect of the invention.

Both the 10 June 1998 application and US '856 disclose the fabrication of piercing structures comprising porous silicon (page 11, lines 2 to 4). The porous silicon is fabricated by etching; the material not etched forms the microneedles (page 11, lines 9 to 10).

The two documents also disclose the use of porous needles (page 14, lines 4 to 6 of the 10 June application) and the fabrication of silicon pore arrays having a variety of different pore sizes (page 14, lines 6 to 12). Pore sizes between 2 nm and 50 nm are expected to be the most useful for drug delivery (page 14, lines 12 to 13). Although some forms of porous silicon are resorbable, the 10 June 1998 application does not disclose the use of resorbable silicon. Therefore the independent claims (and, by definition, the claims dependent from them) are novel.

Both US '856 and the June 98 application disclose the use of porous silicon for the fabrication of microneedles. The general principles relating to the fabrication of microneedles is described in the section (2b) spanning pages 6 and 7 of the 10 June 1998 application.

Allen et al also state the microneedles must have the mechanical strength to remain intact while being inserted into the skin, while remaining in place for up to a number of days, and while being removed (page 6, lines 23 to 26). This passage would lead the skilled person away from using a resorbable material that would resorb once in place, causing it to disintegrate rather than remain intact – just the opposite of Allen's teachings. The use of resorbable silicon would therefore not be obvious.

Applicant observes the US '856 text relating to the fabrication of microneedles is different from the text of the June 98 application. According to the June 98 application Allen et al state the microneedles "must" have the strength to remain intact, whereas US '856 indicates that the microneedles generally "should" have the strength to remain intact.

For the above reasons it is respectfully submitted that the claims of this application define inventive subject matter. Reconsideration, entry of this Amendment and allowance are solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page(s) is captioned "**Version With Markings To Show Changes Made.**"

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____
Arthur R. Crawford
Reg. No. 25,327

ARC:eaw
1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

1. (Amended) A method of transferring a substance into a cell comprising using [porous or polycrystalline] resorbable silicon for conveying the substance into the cell.

2. (Amended) A method according to claim 1 [which comprises using a resorbable or bioerodable porous or polycrystalline silicon] wherein the resorbable silicon comprises porous or polycrystalline silicon.

17. (Amended) A microneedle or micropiercer comprising resorbable [porous or polycrystalline] silicon.

20. (Twice Amended) A microneedle according to claim [17] 34 in which at least a portion of the needle is made substantially completely of porous or polycrystalline silicon.

21. (Twice Amended) A microneedle according to claim [17] 34 in which at least a part of the needle comprises a surface layer of porous or polycrystalline silicon.

22. (Twice Amended) A microneedle according to claim [17] 34 in which a porous or capillary network is provided.

23. (Twice Amended) A needle array having a microneedle or a micropiercer according to claim [17] 34 which further comprises a substance adapted to be conveyed into a cell.

25. (Twice Amended) A needle according to claim [17] 34 which is resorbable or bioabsorbable, or at least part of which is resorbable or bioabsorbable.

26. (Twice Amended) An array of microneedles extending away from a support, in which the microneedles are in accordance with claim [17] 34.

27. (Amended) A cell-entering vehicle for transferring material into a cell, the vehicle comprising, at least in part, [porous or polycrystalline] resorbable silicon, and material to be transferred into the cell.